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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,114	04/07/1999	SHIMON SAKAGUCHI	07898/038001	1911

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/17/2002

Handwritten signature/initials

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,114

Applicant(s)

Sakaguchi, Shimon

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 10, 2002 and 8-2-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The Examiner and Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael C. Wilson, Art Unit 1632.

Applicant's arguments filed 8-02-02, paper number 26, have been fully considered but they are not persuasive. Claim 20 has been added. Claims 10-20 are pending and under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is non-final in view of the new rejections below.

Specification

The specification does not have adequate deposit information for ATCC accession No. BP-7790.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required. Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 C.F.R. 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is

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the same as that described in the specification, and establish that the deposited material was in applicant's possession at the time of filing. In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that,

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of the deposit was made and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

As required under 37 C.F.R. § 1.809(d), the specification shall contain: (1) the accession number for the deposit; (2) the date of deposit; (3) a description of the deposited biological material sufficient to identify it and to permit its examination; and (4) the name and address of the depository.

Summary of the invention

Applicants disclose a founder female derived from BALB/C mice having joint swelling (pg 4, Example 1), a first generation obtained from breeding the founder female with a BALB/C mouse, some of which have joint swelling (pg 5, line 1). A second generation was obtained from breeding a first generation mouse having joint swelling with a BALB/c mouse, wherein some of the second generation had joint swelling. Upon further observation, the males used for breeding

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showed swelling of small finger joints which was not previously noticed (para. 7). Applicants conclude the mutation is incompletely autosomal recessive, i.e. the males used for breeding were heterozygous for the mutation. The mice were "maintained at present as homozygotes" (pg 6, line 2-6).

Claim Rejections - 35 USC § 101

1. Claims 12 and 14 remain rejected and claims 10, 11, 15-17, 19 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The mice and methods claimed are naturally occurring products and methods which is non-statutory subject matter (see Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722) and MPEP 2105). Nordling taught mice derived naturally from the BALB/c strain having symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). Without evidence to the contrary, the naturally occurring mice are "homozygous" because the mice showed signs of disease and because the patent office does not have the means to determine the genotype of the mice. Therefore, the mice claimed are naturally occurring. Since the mice occur naturally, the methods of making the mice occur naturally and any breeding done by the mice occurs naturally.

The declaration filed 5-10-02, paper number 23, which is identical to the declaration filed 8-2-02, paper number 24, has been considered but does not place the application in condition for allowance. While breeding strategies were used to determine how the mutant allele was

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inherited, the claims are not directed to such breeding strategies. The mice claimed can easily be identified by monitoring naturally occurring symptoms of rheumatoid arthritis in the BALB/c strain and do not require breeding strategies. In addition, the homozygous founder animal obtained by applicants occurred by natural breeding strategies. Therefore, the mice claimed are naturally occurring products.

Claim Rejections - 35 USC § 112

2. Claims 10-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13 and 18 recite the limitation of "ATCC accession No. BP-7790" which lacks written description in the application as originally filed. The specification as originally filed did not teach ATCC accession No. BP-7790. The deposit information of SKG embryos provided 2-7-02, paper number 18, does not fulfill the deposit requirements. While the deposit information states the SKG embryos were originally deposited 11-6-02, which is over two and a half years after the filing date of the instant application, applicants have not provided a declaration indicating the chain of custody was maintained since the time of filing, or provide any indication how the embryos deposited correlate to the mice disclosed in the specification. It is unclear if the embryos are first generation, second generation or homozygous mice as described on pg 5-6. It is

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unclear if SKG mice are limited to mice equivalent to the founder female which had macroscopic joint swelling (pg 4, Example 1) or whether SKG mice encompass males that were thought to be normal BALB/c mice but were later found to be carriers of the mutation (pg 5, 7 lines from the bottom). As such, it cannot be determined to which mice the deposited embryos correlate.

Claim 10, filed 5-17-00, paper number 6, is new matter. The specification as originally filed did not contemplate administering compounds to the mice or determining whether a symptom of rheumatoid arthritis was decreased as claimed. Support cannot be found on page 2, 3 or 4 as cited in the amendment.

Claim 15, filed 2-7-02, paper number 21, is new matter. The specification as originally filed did not contemplate mating between SKG mice in a maintained colony repeatedly to produce offspring and screening the offspring for the onset of rheumatoid arthritis. Support cannot be found in Example 1 (pg 5). While the example teaches breeding first and second generation offspring with BALB/c mice (pg 6, lines), the specification does not suggest breeding two mice having symptoms of arthritis.

Claim 17, filed 2-7-02, paper number 21, is new matter. The specification as originally filed did not contemplate "mating between BALB/c mice in a closed colony to produce offspring" or screening the offspring for the onset of rheumatoid arthritis. Support cannot be found in Example 1 (pg 5). While the example teaches breeding BALB/c mice and obtaining an founder female, the specification does not describe the colony as "closed."

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the "mouse strain" claimed cannot be determined. It is unclear if the SKG mice encompass the first generation or second generation as described on pg 5, which are heterozygotes (pg 6, 7 lines from the bottom) or if the SKG strain is limited to homozygous mice.

Claims 12, 15 and 17 are unclear. The phrase "mouse strain from BALB/C mice" does not clearly state the "strain" is not BALB/C, the "strain" has a different genotype or phenotype than the BALB/C strain or that the "strain" is derived from the BALB/C strain. The phrase "homozygous for a trait of developing natural onset of rheumatoid arthritis" is inaccurate because traits are not homozygous; alleles are homozygous at a particular locus. See definitions provided. Nor does the phrase clearly set forth that the mice develop a symptom of rheumatoid arthritis. The metes and bounds of what applicants consider "natural onset" of rheumatoid arthritis cannot be determined. While the mutation in applicants' founder female appears to be spontaneous, it cannot be determined how the mutation occurred. It is unclear whether inducing arthritis using type II collagen in mice is "natural onset" because the immune response in such mice is "natural" and produces symptoms of arthritis.

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The phrase "a mouse from a mouse strain" (claims 13) does not clearly state the "mouse" is not the same as the "mouse strain," the "mouse" has a different genotype or phenotype than the "mouse strain" or that the "mouse" is derived from the "mouse strain." Clarification is required.

The phrase "wherein the rheumatoid arthritis represents one or more symptoms selected from" (claim 14, 16, 19) is unclear. How does rheumatoid arthritis represent symptoms?

The metes and bounds of the mice being mated in claims 15 and 17 is unclear. In claim 15, it is unclear if the claim encompasses mating only two homozygous mice or if the claim encompasses mating a homozygous mouse with a heterozygous mouse. In claim 17, it is unclear if the claim encompasses mating a BALB/C mouse with a heterozygote, or mating two heterozygotes or if the claim is limited to breeding two BALB/C mice that results in a heterozygous mutation.

The metes and bounds of a "closed colony" cannot be envisioned (claim 17).

The phrase "mouse strain from an embryo" (claim 18) is unclear because "the mouse strain" does not come "from an embryo." A strain of mice does not come from one embryo.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 12, 14-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722).

Nordling taught mice derived from the BALB/c strain having symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). Without evidence to the contrary, the mice are "homozygous" because the mice showed signs of disease and because the patent office does not have the means to determine the genotype of the mice. In addition, the phrase "homozygous for a trait" is unclear because mice are not "homozygous for a trait" (see 112/2nd above). "Mating between mice of the isolated mouse strain in a maintained colony" (claim 15) and "repeated mating between BALB/c mice in a closed colony" (claim 17) are equivalent to mating two BALB/c mice.

5. Claims 12, 14-17, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamanaka et al. (US Patent 4,950,741).

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Yamanaka taught a BALB/c mouse that develops antibodies against a rheumatoid arthritis-specific protein which is a trait of rheumatoid arthritis. The trait is "natural onset" because the antibodies are a result of the mouse's natural immune system. The limitation of "homozygous" does not bear patentable weight because traits are not homozygous.

Applicants argument that the mouse of Yamanaka does not develop symptoms of rheumatoid arthritis is not persuasive. Applicants do not point out why the mouse does not develop a symptom of rheumatoid arthritis. The claims do not require the mouse develops every symptom of rheumatoid arthritis.

Conclusion

This action is non-final.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

